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10/670,144	09/23/2003	Esko Alanen	881B.0006.U1(US)	1370	
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			NGUYEN, HUONG Q		
SHELTON, C	1 06484-6212		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/670,144 ALANEN ET AL. Office Action Summary Examiner Art Unit HELEN NGUYEN 3736 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 12 May 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-8.11 and 12 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-8,11 and 12 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Imformation Disclosure Statement(s) (PTC/G5/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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#### DETAILED ACTION

This Office Action is responsive to the amendment filed 5/12/2009. Claim 7 is amended.
 Claims 9-10 are cancelled. Claim 12 is new. Claims 1-8 and 11-12 remain pending and under prosecution.

#### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
  obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over
   Campbell et al (US Pat No. 6370426) in view of Measurement of Dielectric Properties of
   Subcutaneous Fat with Open-Ended Coaxial Sensors by Esko et al (hereinafter referred to as "Measurement").
- 4. Campbell discloses a method for measuring tissue moisture comprising an electromagnetic probe placed on the skin during the measurement and the capacitance of the probe or open-ended coaxial cable is measured to measure the skin water content or edema, best seen in Figure 1 (Col.4: 49-65).
- 5. However, Campbell et al do not disclose the capacitance of the probe as proportional to the dielectric constant of the skin and subcutaneous fat issue and proportional to the water content of the skin, and is silent to the frequency used, and the size of the probe.

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- 6. Measurement teaches that there is a direct known relationship between the dielectric constant of skin and its water content (p.483 see Discussion second paragraph). Measurement also teaches that a frequency of 300 Hz is used to effectively measure the capacitance of the probe for skin measurements to take into account subcutaneous fat tissue (abst). Measurement also teaches that a larger probe (10 mm) is required to penetrate into the subcutaneous fat tissue (p.479 top).
- 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al such that the capacitance of the probe is proportional to the dielectric constant of the skin and the subcutaneous fat tissue, which is further proportional to the water content of the skin, to have the distance between the electrodes of Campbell et al be between 2 and 10 mm, and to measure the moisture at a high frequency between 20 MHz- 500 MHz, as taught by Measurement, to effectively perform the skin measurement by taking into account the subcutaneous fat tissue using a properly sized probe and frequency measurement, which would then provide a tissue edema measurement.
- 8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al in view of Measurement, and even further in view of Sherwin (US Pat No. 4640290). Campbell et al in combination with Measurement disclose the method described above but do not teach the probe secured to the skin by an attachment such as a strap for continuous edema monitoring. Sherwin teaches using straps as an effective method of attaching a probe to the body of a patient (Col.4, line 15-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al as modified by

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Measurement to use a strap attachment, as taught by Sherwin, to aid in securing the probe to the

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skin for continuous monitoring.

9. Claims 5-6 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Campbell et al (US Pat No. 6370426) in view of Measurement of Dielectric Properties of

Subcutaneous Fat with Open-Ended Coaxial Sensors by Esko et al (hereinafter referred to as

"Measurement"), further in view of Penetration of Electromagnetic Fields of an Open-Ended

Coaxial Probe between 1 MHz and 1 GHz in Dielectric Skin Measurements by Esko et al

(hereinafter referred to as "Penetration").

10. Campbell et al disclose a device capable of measuring tissue water content comprising an

electromagnetic probe placed on the skin during the measurement, wherein the capacitance of the

probe is capable of being proportional to the dielectric constant of the skin and the subcutaneous

fat tissue, which is further proportional to the water content of the skin and includes a frequency

unit (53) for measuring the capacitance of the probe and a unit (75) for calculating measured

values and the tissue water content, best seen in Figure 1 (Col.4: 49-65; Col.5: 43-47). However,

Campbell et al is silent as to the frequency used as well as to the distance between the two

electrodes of the probe.

11. Measurement teaches that for skin measurements taking into account subcutaneous fat

tissue, a larger probe a larger probe (10 mm) is required to penetrate into the subcutaneous fat

tissue (p.479 top). Penetration teaches that at higher frequencies above 100 MHz, measured skin

measurements take into account deeper skin layers including the subcutaneous fat tissue and at

lower frequencies, approximately 20 MHz, the measurements only take into account the more superficial layers of the skin (abst).

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- Therefore, it would have been obvious to one of ordinary skill in the art at the time the 12. invention was made to modify the apparatus of Campbell et al such that the two electrodes have a distance of 2-10 mm between, as taught by Measurement, to effectively penetrate into the subcutaneous fat tissue to take said tissue into account for the tissue moisture measurement, which would then provide a tissue edema measurement. Therefore, it would have also been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Campbell et al to have the frequency unit measure the capacitance at different ranges wherein at approximately 20 MHz - 50 MHz, the upper layers of the skin are taken into account while at approximately 50 MHz - 500 MHz, the deeper layers of the skin are taken into account as taught by Penetration, to effectively take into account the desired layers for the edema measurement.
- 13. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malicki et al (US Pat No. 4918375) in view of Measurement or Penetration or Campbell et al.
- Malicki et al disclose a method of measuring substrate moisture comprising: 14 placing a coaxial electrode on a substrate (Col.2: 12-18);

generating a first signal from an oscillator (Col.2: 18-20), wherein the frequency of the first signal is about 20 to 500 MHz (Col.1: 45-46);

transmitting a first portion of the signal of the first signal to the probe and through the substrate (Col.2: 21-24);

 $receiving \ a \ reflected \ signal \ from \ the \ substrate \ through \ the \ probe \ (Col.2; \ 29-31);$ 

leading the reflected signal to a first input of a phase detector,

transmitting a second portion of the first signal to a second input of the phase detector (Col.2: 24-29);

operating the phase detector in a saturated state, wherein signal amplitudes from the reflected signal and the second portion of the first signal form the saturated state;

measuring the phase difference, i.e. time delay, between the reflected signal and the second portion of the signal (Col.2: 31-34);

calculating a dielectric constant from the phase difference (Col.2: 35);

calculating a water content of the substrate based on the dielectric constant (Col.2: 36).

15. However, Malicki et al do not disclose said method used for measuring a water content of the skin such that said probe is placed on the skin during use. Measurement, Penetration, or Campbell et al teach an analogous signal generating method used to measure a water content of the skin wherein a coaxial electrode is placed on the skin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method of Malicki et al to measure the water content of the skin as taught by Measurement, Penetration, or Campbell et al, wherein in use the coaxial electrode is placed on the skin and the frequency of the signal used will penetrate the skin and subcutaneous fat tissue (see Measurement and Penetration above), as an obvious useful application of the method.

### Response to Arguments

16. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Max Hindenburg/ Supervisory Patent Examiner, Art Unit 3736